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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,299	04/14/2005	Nam-Du Kim	Q87387	7860
23373	7590	07/27/2006	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				JAISLE, CECILIA M
ART UNIT		PAPER NUMBER		
		1624		

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/531,299	KIM ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Cecilia M. Jaisle	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 April 2005 and 19 July 2005.  
 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-6 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 14 April 2005 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date 14 April 2005 and 19 July 2005

- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Information Disclosure Statement***

The listing of references in the specification (page 3, line 8; page 4, line 7; page 6, line 14) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications or other information submitted for consideration by the Office and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." These references all appear to provide prior information regarding the claimed process and required starting materials therefor. Applicants are therefor required to provide a proper Information Disclosure Statement citing these references, as well as copies thereof for consideration in the examination of this application. 37 CFR 1.56. The Examiner has not considered any of these references.

***Claim Rejection – 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims recite preparation of risperidone by reacting the hydrochloride salt of the oxime of Formula II with a haloethylpyrimidine of Formula X in an aqueous alkali hydroxide solution having an alkali hydroxide concentration in the range of 20-40%.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Because the claims fail to define the basis for the percentage determination of the aqueous alkali hydroxide (by weight, by volume, by mole, etc.), the claims fail to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Reiter, et al., International Pub. No. WO 03/042212, published May 22, 2003 [Reiter], serves as evidence (page 9, line 15 – page 10, line 4, *inter alia*) that by reacting the hydrochloride salt of the oxime of Reiter's Formula II with a haloethylpyrimidine of Reiter's Formula XIV in the presence of a base at reflux, Reiter did not obtain risperidone, but an oxime intermediate (Reiter's Formula II, page 7, line 3+). Note that the transitional phrase "comprises" in the present claims leaves the claims open to the additional presence of the organic and inorganic bases specified by Reiter (page 10, lines 17-20). Note further that Reiter uses an alkali hydroxide in cyclizing the oxime of Formula II to risperidone. Reiter does not specify the concentration of the alkali hydroxide, but neither do the present claims clearly define the basis for the percentage determination of the aqueous alkali hydroxide (by weight, by volume, by mole, etc.).

Since it is the essence of the scientific method that reacting the same reactants in the presence of the same reagents at the same conditions will produce the same result, Reiter stand as evidence that the present claims do not specify all of the reaction parameters required to ensure preparation of the final product risperidone rather than the oxime intermediate.

***Claim Rejections – 35 USC §§ 102 and 103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Reiter.

The following explanation supports the 35 U.S.C. 102(a) rejection. Reiter describes (page 9, line 15–page 10, line 4, *inter alia*) the reaction of the hydrochloride salt of Reiter's Formula II oxime with a haloethylpyrimidine of Reiter's Formula XIV in the presence of a base at reflux. The transitional phrase "comprises" leaves the present claims open to the additional presence of the organic and inorganic bases specified by Reiter (page 10, lines 17-20). Reiter does not specify the concentration of the alkali hydroxide, but neither do the present claims clearly define the basis for the percentage determination of the aqueous alkali hydroxide (by weight, by volume, by mole, etc.). Further, because Reiter teaches risperidone as the ultimate desired final product of his reaction (page 10, lines 5-16) and teaches the use of alkali hydroxide (page 10, lines 5-9) to obtain risperidone, Reiter anticipates the reaction of the present claims.

The following rational supports the alternative 35 U.S.C. 103(a) rejection. A person of ordinary skill in this art would be motivated to react the hydrochloride salt of the oxime of Reiter's Formula II with a haloethylpyrimidine of Reiter's Formula XIV in the presence of aqueous alkali hydroxide, because Reiter teaches (page 10, lines 5-9) that the oxime of Reiter's Formula II cyclizes in the presence of an alkali hydroxide, alkali carbonate or alkali-C1-4-alkoxide. Reiter does not specify the concentration of the alkali hydroxide, but neither do the present claims clearly define the basis for the percentage determination of the aqueous alkali hydroxide (by weight, by volume, by mole, etc.).

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Reiter further teaches (page 10, lines 5-16) that risperidone, not the oxime of Reiter's Formula II, is the desired final product. Therefore, an artisan, ordinarily skilled in this art, would be motivated to use alkali hydroxide as the base throughout the reaction scheme of Reiter with the expectation of thereby preparing risperidone.

Applicants cannot rely upon the foreign priority papers to overcome these rejections because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

***Conclusion***

Claims 1-6 are rejected; no claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cecilia M. Jaisle, J.D. whose telephone number is 571-272-9931. The examiner can normally be reached on Monday through Friday; 8:30 am through 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JOW/cmj

  
DEEPAK RAO  
PRIMARY EXAMINER